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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,705	02/28/2002	Tae-Hyun Kim	DE-1347	4896

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EXAMINER	
HENDRICKS, KEITH D	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

15

Office Action Summary	Application No.	Applicant(s)	
	10/087,705	KIM ET AL.	
	Examiner	Art Unit	
	Keith Hendricks	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-18 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of koji microorganisms of the genus *Aspergillus* or *Bacillus*, does not reasonably provide enablement for the "culturing [of] soybean hypocotyl inoculated with a microorganism." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The production of koji, as traditionally performed for centuries, requires the presence of specific types of microorganisms, especially that of the genus *Aspergillus*. The arbitrary addition and culturing of the soybean hypocotyl substrate with any random and unspecified microorganism would not be expected to result in a koji type material which would be effective for subsequent use in other foodstuffs. In fact, the vast majority of microorganisms encompassed by the language of claim 1 would be expected to be detrimental to the substrate and/or to persons consuming the product. Therefore, the scope of enablement of the claims is not met by the teachings and guidance of the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 9-18 and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite for the recitation of the steps of "pre-culturing and culturing". The metes and bounds of these steps are not set forth such that one skilled in the art would be adequately apprised of the invention, and further, the distinction of each step is unclear, one from the other. In other words, it is unclear as to what is encompassed by the steps of "pre-culturing" and "culturing".

Claim 9 is indefinite for the recitation of the koji containing soybean hypocotyl "in an amount of 5 to 100% based on the weight of the koji." As the nature of koji itself requires the presence of microorganisms (for example, in amounts of "0.01 to 10 wt %", as recited in claim 2), the koji of claim 9 then could not be 100% soybean hypocotyl. This does not allow for the presence of the microorganisms, which are required by definition.

Claim 10 recites the use of soybean hypocotyl koji as a "raw material." However, as koji is a fermented composition produced by several processing steps, the term "raw material" would not appear appropriate, and appears to be misleading.

Claim 12 recites the limitation "the cultivation", and depends from claim 10. However, there is insufficient antecedent basis for this limitation in claim 10.

Claim 10 provides for the use of soybean hypocotyl koji, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 11-18 and 25-29, dependent upon claim 10 and yet failing to further limit and define the "use", are thus also rejected.

Claims 10-18 and 25-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

Claim 7 is objected to because of the following informalities: in line 1, the term "*Basillus*" should be "*Bacillus*". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

i) Claims 1 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Asao (JP 40-3039059, abstract).

Asao discloses the production of a fermented soybean hypocotyl, which is produced by the fermentation of the hypocotyl by *Bacillus* or *Aspergillus* microorganisms.

ii) Claims 1-2, 7-11, 16, 18, 19 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Takebe (US PAT 6,045,819).

Takebe discloses a "process for preparing a product containing a healthful component" wherein "koji mold is inoculated on a pulse crop to effect koji preparation". Columns 5-6 disclose that traditional miso and soy sauce production utilizes the addition of a high salt content subsequent to koji production, whereas the disclosed method overcomes this issue. At column 7, it is stated that

> As a starting material of the product of the present inventions pulse crops may be used. In addition to pulse crops such as soybean, there may be used meal or cake thereof [for example, soybean meal (defatted soybean)], hypocotyl thereof, a soy protein extract (dried soy-milk powder), a soy protein isolate and the like.
> Of these, hypocotyl, a soy protein extract and a soy protein isolate contain isoflavone compounds in large amounts and thus these are suitable as a starting material for preparation of a product containing aglycones of isoflavone compounds, in particular, genistein in high concentrations.

Columns 8-10 disclose method steps for the preparation of fermented koji using these starting materials. Column 10, lines 30-38 states that the koji microorganisms utilized are those used in traditional fermented foodstuffs, "for example, those classified as *Aspergillus* genus such as *Aspergillus usamii, Aspergillus kawachii, Aspergillus awamori, Aspergillus saitoi, Aspergillus oryzae* and *Aspergillus niger*." Proportions of the starting materials are provided at columns 11-12, including the amount of microorganisms, namely $8x10^7$ koji spores/g (mid col. 11), and column 12 (starting at line 38), where it is shown that the koji mold is used in an amount of 0.1% (250.5 g total amount of ingredients, with 0.3 g of koji mold). Column 15 teaches that the resultant koji may be used as follows:

> The product of the present invention includes products as such (plain products) which are made from a pulse crop as a starting material, applied products made of the plain product (or containing the plain product as an ingredient), for example, foods, livestock feeds and aquacultural feeds, cosmetics, diets of pets, precursory products for pharmaceutical preparations.
> The product made from a pulse crop as a starting material which is prepared in accordance with the process of the present invention may be a food having an extremely low salt content, because it is prepared without being salinized with common salt. Accordingly, the product can be ingested in a sufficient amount when served as a food.

Thus the instantly-claimed invention is anticipated by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-6, 12-15, 17, 20-23 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takebe, in view of Steinkraus.

Takebe is taken as cited above.

Steinkraus discloses traditional steps in production of soy sauce. These steps include the initial production of a koji, and the subsequent mixing with wheat and further microorganisms such as *Saccharomyces rouxii* or *Pediococcus soyae*. To produce the koji, soybeans are first soaked, then steamed, mixed with wheat and inoculated with 1-2% of the koji microorganism (*Aspergillus*), and cultured at a temperature between 25-35°C for approximately 2 days (pages 512-514). Once the koji is prepared, it is traditionally mixed with salt brine, and pure cultures of *Saccharomyces rouxii* or *Pediococcus soyae*.

Thus, the production of koji using soybean hypocotyl as a starting material, and subsequent use of this material to produce soy sauce or soybean paste, would have been obvious to one of ordinary skill in the art, given the teachings of the primary and secondary references. The production of koji using soybean hypocotyl as a starting material was taught by Takebe, as stated in the previous rejection, above. The specific parameters of the instantly-claimed method steps would not provide a patentably-distinct invention over the known steps disclosed by the references. Furthermore, Takebe recognized the

advantage of using the substrates and methods disclosed therein, including that of soybean hypocotyl, for use in producing a koji product which would not require the addition of high amounts of salt. Takebe suggested the incorporation of the fermented koji product into traditional fermented foodstuffs, including the production of soy sauce and miso (soybean paste). Steinkraus discloses known traditional steps for producing soy sauce from a soy-containing koji, and thus claims 12-15 and 17 would not have involved an inventive step for one of ordinary skill in the art to have produced.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KEITH HENDRICKS
PRIMARY EXAMINER